

**Introduction**

- The National Institute for Health and Care Excellence (NICE) severity modifier (SM) was introduced in February 2022. It places a higher value on health gains in indications of higher severity. Severity is assessed as a shortfall in quality-adjusted life years (QALYs) for patients on the current standard of care (SoC) versus the general population (PMG36).<sup>1</sup>
- The NICE SM replaced the End-of-Life (EoL) criteria (gid-tag387), which placed a higher value on life-extending treatments for patients with median overall survival (mOS) of <24 months on the current SoC.<sup>2</sup>
- The objective of this research was to compare the NICE classification of disease severity under the previous EoL guidance with the new SM method to understand: (i) changes in NICE valuation of QALYs in cancer patients, and (ii) SM application across tumour types.
- Lower valuation of cancer patients' QALYs results in a higher incremental cost-effectiveness ratio (ICER), which is likely to reduce access to innovative cancer treatments.

**Methods**

Seventy-three indications across 5 tumour areas with high unmet need were evaluated: breast, colorectal, gastroesophageal (GOJ) and gastric cancer, non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC), distinguishing between biomarker subpopulations and lines of treatment. The EoL criterion was applied to indications with mOS <24 months for the current UK SoC. Survival with SoC was sourced from published literature and NICE technology appraisals (TAs).

The SM (no weight [×1.0], ×1.2 or ×1.7) was estimated in line with NICE methods, using a standard 3-state partitioned survival model with indication-specific survival outcomes and health-state utilities based on published literature and TAs, respectively. For simplicity, all survival extrapolations adopted the exponential curve. Whilst simplistic, the assumption is considered conservative given that (i) it applies to both arms, and (ii) exponential curves assume a limited tail. QALYs for the general population were estimated using Hernández et al.<sup>3</sup>

**Results**

Twenty cancer indications (41%) that met EoL were 'downgraded' (did not qualify for the ×1.7 SM) (Figure 1). In contrast, only 2 indications (8%) that did not meet EoL potentially qualified for the ×1.2 SM. Breast and lung cancer had the highest percentage of downgraded indications: 60%, 50% and 33% for breast cancer, NSCLC and SCLC, respectively (Figure 2). As a result, NICE no longer considers some cancers with mOS <15 months a highly severe disease (e.g., 1L HER2+ gastric, 2L NSCLC in PDL1>50%, 3L EGFRm NSCLC), adding to patients' concerns about the SM method.<sup>4</sup>

**Conclusion**

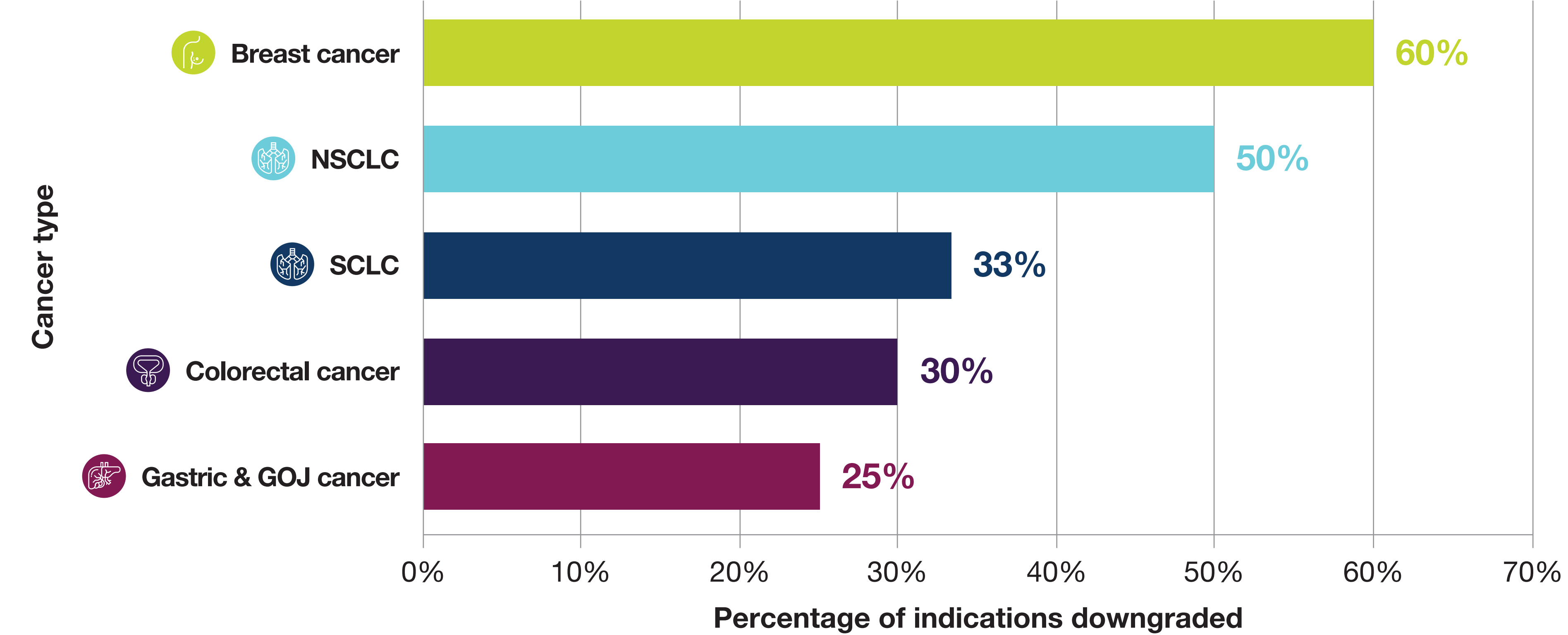
- The findings indicate that the new NICE SM downgrades severity of cancer relative to the previous EoL criteria.
- Breast and lung cancer indications were most affected by this downgrade.
- As a result, the switch to the SM approach decreases the value placed by NICE on QALYs in cancer patients. Lower valuation of cancer patients' QALYs results in a higher ICER, reducing access to innovative cancer treatments.<sup>5</sup>
- These findings underscore the need for the SM methodology to incorporate societal preferences and patient concerns to secure access to treatment for patients with low life expectancies.

Figure 1: Comparison of applicability of EoL and SM criteria



Footnotes: 'High severity (x1.7)' is indicated in pink, 'medium severity (x1.2)' is in orange and 'no weight (x1.0)' is in grey. Indications eligible for EoL are outlined in red. The half-and-half boxes represent indications where the absolute and proportional shortfall were sensitive to patient demographics. As such, these were counted as the lower of the 2 SMs on the assumption that NICE would not award the higher.

Figure 2: Percentage of indications with downgraded severity, by cancer type



Footnotes: 'Downgraded indications' are those that qualify for EoL but not x1.7 SM. NSCLC included 1 indication for which the absolute and proportional shortfall were sensitive to patient demographics. As such, this was counted as a x1.2 SM on the assumption that NICE would not award x1.7.

Abbreviations

1/2/3/4L: first-/second-/third-/fourth-line; BRAF: B-Raf proto-oncogene serine/threonine kinase; CLDN: Claudin; EGFRm: epidermal growth factor receptor-mutant; EoL: end-of-life; EQ-5D: EuroQOL 5D; GOJ: gastroesophageal; HER2: human epidermal growth factor receptor 2; HR: hormone receptor; ICER: incremental cost-effectiveness ratio; KRASm: K-rat sarcoma-mutant; MSI-H: microsatellite instability-high; MSS: microsatellite stable; NICE: National Institute for Health and Care Excellence; NSCLC: non-small cell lung cancer; NSQ: non-squamous; PDL1: programmed death-ligand 1; QALY: quality-adjusted life year; R: resectable; RASwt: rat sarcoma wild-type; SCLC: small cell lung cancer; SoC: standard of care; SM: severity modifier; SQ: squamous; TA: technology appraisal; TNBC: triple-negative breast cancer; UK: United Kingdom; UR: unresectable.

References

<sup>1</sup>NICE (2025). NICE health technology evaluations: The manual. Available at: <https://www.nice.org.uk/process/pmg36/resources/nice-health-technology-evaluations-the-manual-pdf-72286779244741> [Last accessed 23 Sept 25]. <sup>2</sup>NICE (2009). Appraising life-extending, end of life treatments. Available at: <https://www.nice.org.uk/guidance/gid-tag387/documents/appraising-life-extending-end-of-life-treatments-paper2> [Last accessed 23 Sept 25]. <sup>3</sup>Hernández Alava M, Pudney S, Wailoo A. Estimating EQ-5D by Age and Sex for the UK. NICE DSU Report. 2022. <sup>4</sup>Breast Cancer Now (2025). Setting the bar too high: How the NICE severity modifier is blocking access to life-extending treatments. Available at: [setting-the-bar-too-high-report.pdf](https://breastcancer.org.uk/about-us/media/statements/we-respond-to-nice-board-decision-to-not-make-changes-to-severity-modifier) [Last accessed 23 Sept 25]. <sup>5</sup>Breast Cancer Now (2024). We respond to NICE board decision to not make changes to severity modifier. Available at: <https://breastcancer.org.uk/about-us/media/statements/we-respond-to-nice-board-decision-to-not-make-changes-to-severity-modifier> [Last accessed 23 Sept 25].

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Disclosures

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